



DEPARTMENT OF HEALTH AND HUMAN SERVICES

D1279B
Food and Drug Administration
Atlanta District Office
HFI-35

60 8th Street, N.E.
Atlanta, Georgia 30309

March 21, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Gregory Conner, M.D.
Medical Director of Radiology
The Byerly Hospital
413 East Carolina Ave.
Hartsville, SC 29550

WARNING LETTER

Inspection ID: 195271

Dear Dr. Conner:

Your facility was inspected on January 9, 1997 by a representative of the South Carolina Department of Health and Environmental Control (SCDHEC) acting on behalf of the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with certain Quality Standards for Mammography as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

No processor quality control records were present for the [REDACTED] processor.

The specific deficiencies noted above appeared under the Level 1 heading on your MQSA facility Inspection Report, which was issued at the close of the inspection. These deficiencies may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 2 noncompliances that were listed on the inspection report provided to you at the close of the inspection. These Level 2 noncompliances are:

The number of masses scored in the phantom image was 2.5 and did not meet the required number of 3.0 (the phantom was re-evaluated by FDA and determined to be in compliance).

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating

and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- ▶ Impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.
- ▶ Suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- ▶ Seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

the specific steps you have taken to correct all of the violations noted in this letter;

each step your facility is taking to prevent the recurrence of similar violations;

equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

sample records that demonstrate proper recordkeeping procedures, if the noncompliances that were found relate to quality control or other records. (Note: Patient names or identification should be deleted from any copies submitted.)

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which corrections will be completed.

Please send the original copy of your response to (NOTE: If phantom image is required for corrective action, please submit to SCDHEC):

U.S. Food and Drug Administration
Compliance Enforcement Branch
60 8th St., NE
Atlanta, GA 30309

With a copy to:

SCDHEC
Bureau of Radiological Health
2600 Bull St.
Columbia, SC 29201

and

Debbie Hahn
FDA
5701 Executive Center Drive, Suite 104
Charlotte, NC 28212

You may choose to address both FDA and State requirements in your response. If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Debbie Hahn at 704-344-6116.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Ballard H. Graham", written over a horizontal line.

Ballard H. Graham, Director
Atlanta District